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FDA—Protector of the Drug Industry

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The following is a transcription of the July/August 1963 issue of Dr. Royal Lee's *Applied Trophology* newsletter, originally published by Standard Process Laboratories.

FDA—Protector of the Drug Industry

The Food and Drug Administration may have dragged its feet in pulling back thalidomide, but it is waging serious war against fish flour, which it acknowledges a wholesome product, but "offensive to the senses." Here is a documented story that will make you think more than twice about taking drugs, after realizing that your very life may lie in the hands of the FDA.

From *Prevention*, June 1963: "The more we have examined the handling of the new drugs by the Food and Drug Administration, the more we have been surprised, shocked, and disappointed."

These words of Senator Hubert Humphrey, spoken last October, summarize the feelings of the U.S. Senate Subcommittee on Reorganization and International Organizations, which is taking a good look at FDA practices. What they found was shocking, indeed—shocking enough to reinforce the Kefauver-Harris drug reform bill, which gave drug-withdrawing powers to an authority higher than the FDA, forced the drug companies into truthful advertising, and protected doctors' patients from becoming unwitting guinea pigs for new drugs.

This tighter control on what seems to be an FDA-pharmaceutical alliance, although a step in the right direction, was no more than a minor dent struck in the side of a powerful government agency in desperate need of a major shake-up at its highest levels. Actually, the greatest good accomplished by those Senate hearings of 1962 was to bring to the public a basic truth long known to readers of *Prevention*: that the Food and Drug Administration, sworn to protect the American public, gives more protection to the interests of the huge drug companies, which have been reaping tremendous profits while knowingly endangering the public safety. As one ex-FDA medical officer testified before the hearings, in some of its activities, the FDA has become "merely a service bureau" for the drug industry.

Shocking Truths

Before the investigation, attacks upon the FDA were dismissed as coming either from medical quacks, food faddists, or outright communists seeking to undermine the government—all convenient terms that were supposed to discredit any accusation by assassinating the character of the accuser. Now, however, at least a part of the truth has been dragged from beneath the carpet, and there is every indication that the worst truths are yet to come. In the past year, honest reporters and forthright FDA medical experts—some of whom had to resign their positions to speak the truth—have established these points:

1. New drugs have been routinely passed for marketing by the FDA before being tested on human beings—even before being tested sufficiently on laboratory animals.
2. The devastating injuries, cripplings, and deaths caused by these drugs have often gone unreported to the When they were reported, FDA officials sometimes waited for months at a time before finally withdrawing the offending drug from the market.
3. FDA physicians who tested drugs were put under tremendous pressure to pass them quickly and without close

inspection—not only by the drug manufacturers but by *top-level FDA executives.*

4. In the FDA, a new and untested drug can be passed by a medical officer without review by any of his colleagues. But in order to deny approval of a new drug, that officer must have the unanimous support of the Chief of the New Drug Division, the Director of the Bureau of Medicine, the Commissioner, and usually also the Director of the Bureau of Enforcement and the General Counsel's office.
5. Government agencies have been paying drug companies hundreds of thousands of dollars for the "privilege" of testing new drugs, which are then passed back to the drug companies, approved quickly by the FDA, and sold to the public under medical prescription at tremendous profits. In other words, the government has been doing the work of the drug companies, paying heavily for the opportunity, then closing its eye to the exorbitant prices that the pharmaceutical firms charge the public for these drugs.
6. Lastly, in an unholy alliance with the AMA, the FDA has used its image as the "protector of the people" to launch a vicious attack on beneficial vitamins and food supplements and has used every legal trick possible to stall public trial of successful but unapproved treatments of killing and crippling diseases, such as the Gerson cancer treatment, Krebiozen, the Coca dietary pulse technique, and the Turkel treatment for mongolism.

If these facts are difficult for you to believe about your Food and Drug Administration—which you are supporting with your tax dollars—you won't be in doubt for very long after reading this evidence, on Senate record, testified by Senator Humphrey and by ex-FDA medical officers:

Senator Hubert Humphrey: "Often, testing has been going on in a manner which should have sent shivers down the spine of the medical profession…drugs intended for use by victims of chronic diseases—day after day, year after year—were released by FDA even before—I repeat—before—chronic toxicity tests had been completed on animals… shocking reports of injuries and deaths to test patients, as received by drug companies, have often gone unreported to FDA, or have been downgraded by skillfully contrived half-truths, or have been reported accurately to FDA but virtually ignored…Drugs have been approved that FDA now admits should never have been approved. Drugs have been kept on the market long after FDA admits they should have been eliminated."

Dr. Louis Lasagna, Johns Hopkins University: "I have been approached to start human testing of a drug with the only information available being the amount of drug necessary to kill 50 percent of mice receiving the drug in one intravenous dose."

Dr. Barbara Moulton, **Ex-FDA Medical Officer:** Orders came "from above" for medical officers to certify drugs about which they had doubts, the justification being that the manufacturers should "be in a much better position to judge their safety" (*The Reporter*, March 28, 1963).

Dr. John O. Nestor, FDA Medical Officer: The Food and Drug Administration has permitted sale of new drugs "immediately hazardous to the public health" and left them on the market months after they showed signs of dangerous side effects. In doing this, superiors overruled expert medical opinion (*Associated Press*, March 21, 1963).

The result of the shocking handling of new drugs by the FDA has been told and untold suffering, known and unknown deaths. Were this just the result of inefficiency, of shoddy examining processes, or of sheer official ignorance, it could be at least partially understood, although not excused. But it is not. This suffering and death has apparently been allowed to happen through FDA's effort to cooperate fully with pharmaceutical firms seeking to market new drugs as quickly as possible for maximum financial gain. Public welfare seems to get little consideration when it conflicts with the welfare of a big industry.

Here are some of the harmful drugs that have been allowed to fall into public usage, either on the pharmaceutical prescription market or on an experimental basis that led to their being administered to hundreds or thousands of patients by individual physicians:

Delvex: Product of Eli Lilly & Co. A drug for treatment of certain parasitic infestations of the intestines; caused a high incidence of gastrointestinal and other symptoms and was strongly suspected of causing as many as six deaths. Withdrawn from the market.

Kevadon: Chemical name thalidomide. Product of William S. Merrell Co. First tested by Smith, Kline and French Laboratories in 1956–57, which reported no deformities among 875 patients; FDA was ignorant of SK&F tests. Merrell filed NDA (new drug application) September 1960, distributed 2½ million tablets to 1,267 physicians for experimental use. Merrell learned on November 11, 1961, that the drug was associated with birth deformities in West Germany. FDA, learning of danger, did nothing.

Merrell, in early December 1961, sent warning letter to physicians who had received the drug and who had reported results using it; physicians who had not reported (90 percent) were not warned, still had the tablets.

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Three months later, Merrell wrote to this 90 percent with a warning to destroy thalidomide tablets. More than 21,000 persons in United States received thalidomide from domestic or foreign sources; at least 9 women bore children without arms and legs because of it. Credit to Dr. Francis Kelsey, who had refused to pass on thalidomide NDA for more than a year, while doing intensive research, thus averting a national tragedy.

MER/29: Product of William S. Merrell Co. A drug intended for reducing blood cholesterol. NDA filed July 1959. Merrell immediately contacted FDA medical officer assigned to case. Officer judged application "incomplete" in March 28, 1960, because of "incomplete clinical studies in full details." April 19, 1960, MER/ 29 was passed as safe by same officer. Afterwards, reports filtered in to FDA stating that MER/29 caused cataracts, baldness, changes in hair and skin color, and caused formation of desmosterol—a cholesterol-like substance—in blood vessels. Nineteen months later, November 16, 1961, FDA scientists recommended that MER/ 29 be withdrawn, but FDA top officials still refused to withdraw drug. On market for *two years,* taken by more than 300,000 people. March 1962, Humphrey subcommittee was told that Merell's initial safety reports "had been falsified." In April, Merrell recalled the drug. In May, FDA Commissioner Larrick suspended the application.

The case histories of harmful drugs passed by the FDA or allowed to be used experimentally on unknowing doctors' patients could go on and on. *Ilosone*, an Eli Lilly product, and *Tao* (J.B. Roerig) are two antibiotics that can cause liver injury when taken for longer than ten days. *Altafur* (Norwich Pharmacal Co.), an antibacterial agent used to fight staphylococcus infection, was withdrawn from the market after causing serious side-effects; as were *Dornwal* (Maltbie Labs), a tranquilizer; *Entoquel* (White Labs), an atropine-like drug used to control diarrhea in children and infants; *Flexin* (McNeil Labs), a drug used to treat chronic gouty arthritis; *Monase* (Upjohn), which was claimed to relieve mental depression, and others.

Some of these drugs were allowed to be placed upon drugstore shelves, while samples of all were mailed to thousands of doctors, supported by promotional literature and medical journal advertising. The physicians, who had no way of knowing any of the drugs were harmful, prescribed them to patients in the hopes of relieving assorted ills. The patients, placing full faith in their family doctors, naturally had no question about the drugs. Usually, in fact, when the new drugs were used on an experimental basis by the doctor, the patient was not aware that he was entering into a medical experiment.

It is not, then, very difficult to lay the blame. The patient knows little or nothing, although he is the one who suffers, both in health and financial loss, and even in life. The doctor can assume part of the blame, for dispensing untested drugs to patients without their knowledge or consent. The drug companies, of course, must assume a large share of the burden for improper testing, slanted and falsified reports, and pressuring FDA medical officers. One thing in their favor, however, is a basic honesty—they are in business solely for profit and are not keeping it a secret.

The lion's share of the blame rests squarely upon the FDA and, more precisely, upon the high-ranking officers of that organization. Working in a structure that in itself heavily favors the interests of the drug industry, FDA officials have been shown to tip the scales even further by bending their own rules to pass new drugs and by making very uncomfortable the lives of any medical officers who do not cooperate with their wishes and with those of the drug firms. They have allowed representatives of the drug firms to camp in the offices of the medical officers while waiting for approval of new drug applications, arguing every step of the way with FDA researchers. They have failed to recall drugs even when their harmfulness has been indicated without doubt. Clearly, they have failed in their sworn duty to safeguard the American public from unsafe drugs.

How Close the Tie?

The results of the relationship between the FDA and the drug industry rouses a natural degree of curiosity about the exact nature of that relationship. There has been little evidence of any direct "payoffs." However, when we trace the careers of men in the drug industry, we find their paths weaving in and out of government and public health agencies with amazing regularity. We find many instances of conflicting interests among government health personnel.

One physician, for example, who worked on the application for Marsilid, a drug later found to lead to hepatitis, was shortly afterward hired by Marsilid's maker, Hoffmann-La Roche.

The former head of FDA's Division of Antibiotics, Henry Welch, was writing articles for professional journals—usually a noble and scholarly endeavor, except that Mr. Welch was found to have earned a profit of approximately $228,000 in this sideline, paid to him by the very firms he was supposed to be regulating.

From a very fine article in the periodical *The Minority of One* (February 1962), we find these instances of the happy family relationships enjoyed by the FDA, the drug industry, the American Cancer Society, the American Medical Association, and other public health agencies:

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> "Former Surgeon General Leonard Scheele is now president of Warner-Lambert (a drug manufacturer)… James Adams, an international investment banker (also named by *Medical World News* as one of the few in medical research control), is on the Board of Directors of the American Cancer Society as well as on the board of Warner-Lambert; Matthew Rosenhaus, president of Pharmaceuticals, Inc., is the prime mover of the newer Eleanor Roosevelt Cancer Research Foundation; the present chairman of the AMA Council on Foods and Drugs, Dr. William C. Spring Jr., is a recent employee of Pfizer (a leading drug manufacturer); Dr. Austin Smith, president of the Pharmaceutical Manufacturers Association, is a former editor of the *Journal of the American Medical Association;* Dr. Richard S. Schreiber, a vice president of the Upjohn Company, is a member of the National Advisory Cancer Council; Dr. Alexander M. Moore of the Parke-Davis Co. is a member of the Chemistry Panel of the National Cancer Institute; Dr. Andrew C. Bratton Jr. of Parke-Davis is a member of the Drug Evaluation Panel of the National Cancer Institute, as is Dr. Karl A. Folkes of Merck, Sharpe and Dohme (another drug manufacturer)."

From this list—hardly all-inclusive—we can get an idea of the cordial relations enjoyed by men of medical research, of government health agencies, and of the drug industry. But perhaps the most amazing sign of fraternal brotherhood is the recent news that, this May, FDA Commissioner George P. Larrick is to receive an honorary membership into the American Pharmaceutical Association. Seldom have we seen such a warm display of affection and gratitude as that shown by the drug industry to its supposed "regulator," the FDA.

Squelching the Independent

While the FDA has been fraternizing with the drug companies on one hand, on the other it has been using its judicial and enforcement powers to squelch small vitamin manufacturers and independent medical researchers not approved by both the drug firms and the American Medical Association. The AMA, of course, wields tremendous influence upon the policies of the FDA, many of whose personnel are physicians. If the AMA wants to ruin the reputation of any ethical physician, it can do so. If one of its drug advertisers wants a drug on the market, the AMA is suspected of cooperating to get that drug on. Thus, the AMA, the drug industry, and the FDA work with interlocking arms— under the propaganda leadership of the AMA—to protect their mutual interests.

One broad result of this health monopoly is that the FDA can reinforce its image as a public protector warring against "health quackery" while protecting favored private interests. The other result is that the American public is a three-time loser: 1) it is being deprived of vital nutritional knowledge and perhaps even of the right to choose which vitamins to buy; 2) it is contributing, through tax dollars, to the profits of the drug companies; and 3) it is being deprived of access to independent medical research and aid that might well lead to a significant decline or elimination of some major diseases, such as cancer, diabetes, and mongolism.

The Turkel Story

One example of a legitimate medical research suppressed by the health monopoly is the Gerson treatment for cancer, the story of which appears in this issue.

Another example is that of Henry Turkel, MD, of Detroit, Michigan, who has never been able to persuade the AMA to give his mongolism [Down syndrome] treatment a fair trial, even though his experience in treating more than sixty mongoloid patients has met with gratifying success. Dr. Turkel, it seems, has not shown proper respect for the AMA, and is now being punished for such heresy.

Dr. Turkel has been engaged in mongolism research for seventeen years, during which time he has evolved a medical treatment that has apparently met with a significant degree of success. In the past, mongolism was viewed fatalistically, and parents of mongoloid children were told to learn to live with their tragedy. Unfortunately, most physicians still think of mongolism in these terms, either because they do not know of Dr. Turkel's treatment or because they have been led by the AMA to view it with doubt and suspicion.

Dr. Turkel's approach is to return the mongoloid patient to as near normal a life as possible, through a series of treatments with what he has termed the "U" series of drugs. The treatments are said to gradually alter the mongoloidal abnormalities and change the various abnormal organs until each approaches normality. Through this treatment of the whole system, the brain tends to return to normality also, enabling the patient to be capable of learning and functioning in society at a relatively normal level.

Dr. Turkel's "U" series of drugs are five combinations, each administered to relieve a specific physical disability that is part of the general condition presented by mongolism. Each of the drugs and vitamins of the "U" series has been used previously in medicine and has been accepted as safe. Yet, despite the safety and seeming effectiveness of the "U" series, the AMA has refused to recognize the treatment, and the FDA refused to clear the "U" series combinations for standard medical usage for more than two years, finally relenting this year to permit the drugs to be used only on an experimental basis. Unlike the large drug firms, however, the individual researching physician

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soil health and nutrition cannot hope to afford to give away free the drugs in the quantities necessary to establish a large-scale test of his treatment. And, under FDA regulations, Dr. Turkel cannot charge patients for the drugs he administers to them. This is a bureaucratic spiderweb making it impossible for a doctor to experiment with a new treatment except through a wealthy pharmaceutical company. If the profits don't look big enough to the drug company, the doctor is stymied.

This is a clear-cut case where both AMA and the FDA consciously are using their powers to prevent further trial and possible acceptance of the first medical treatment ever claimed effective against mongolism. Why would these organizations purposely try to stymie this new treatment? Why would they refuse to make the proper tests to judge the treatment's effectiveness? And why would the FDA use its powers to block use of "U" series of drugs—all of which had been used previously and were proven safe—in light of repeated instances of FDA's passing dangerous drugs that were never even fully tested for safety on animals? The answer is that Dr. Turkel has acted independently of the AMA, and is developing a treatment that cannot be patented, and consequently holds no promise of big profits for anyone. For this he has felt the wrath of the health monopoly.

Other Independents

There have been other instances of experimental drugs being suppressed by the FDA for no apparent or logical reason. Laetrile, a cancer-treating drug, has been turned down by the FDA even though, according to a UPI release of March 10, 1963, "No one at FDA challenges the safety of the drug." The FDA's wrath, it appears, stems from a personal vendetta against Laetrile's sponsors, Ernest T. Krebs Jr. and the John Beard Memorial Foundation. These sponsors were fined in San Francisco for violating new drug provisions of the FDA in connection with an entirely different drug. Krebs was thus prohibited from making interstate shipments of any new drugs—which included Laetrile. Krebs' fatal error was to permit information about Laetrile to be published in a national Sunday supplement magazine. This practice of publicizing medical information in the public press—when not cleared by the AMA—is frowned upon most heavily at the AMA, and thus also at the FDA. Following form, FDA officials denounced the article as "what amounts to practicing medicine in print." If done with AMA approval, as frequently happens, there would have been no comment.

The Fish Flour Front

Perhaps the most ludicrous of all FDA actions in the recent past has been its campaign against fish flour. Fish flour, a rich nutritional supplement, has caught the imaginations of many officials of the Kennedy administration because it shows great promise as an inexpensive and rich supplement to the impoverished diets of peoples in underdeveloped nations. With the inexpensive fish flour, deficiency diseases the world over could be arrested to a great degree. The FDA, however, has put its foot down on a certification request from the VioBin Corporation of Monticello, Illinois, because it considers fish flour offensive to the senses. Because the supplement contains the whole fish (although it is a tasteless white powder), the FDA believes it is not suitable for the squeamish American housewife. And for this reason, VioBin cannot distribute fish flour.

Could anything be more ludicrous? While the FDA has been pressuring its own medical officers to send dangerous drugs untested onto the market, it has been halting the use of a natural food supplement for esthetic reasons! *Science* magazine commented upon the fish flour situation in its March 8, 1963, issue, saying:

> "In quiet and informal ways, various administration officials, including Secretary of the Interior Udall and the President's Science Adviser, Jerome Wiesner, have tried to persuade FDA to change its stand, but the agency is quite independent *when it chooses to be* (italics ours), and it has stood its ground."

The FDA, in our opinion, has conducted itself repeatedly in direct opposition to its intended government function. Supposed to regulate the drug industry, it has been the industry's close friend and confederate, while at the same time denying the public the possible fruits of legitimate individual medical research and treatment and attempting to destroy the natural food supplement industry. We believe it is the solemn duty of every thoughtful American to write to his Congressman, expressing his opinion about the actions of Mr. Larrick and the FDA, and also to write to the Honorable Hubert Humphrey, United States Senate, Washington 25, DC, to give him moral support in his current investigation of FDA practices.

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